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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,367	10/24/2003	Audrey Minden	0575/55311-AZ-PCT-US/JPW/	2322

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NEW YORK, NY 10036

EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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07/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/693,367	Applicant(s) MINDEN, AUDREY	
	Examiner Michael Szperka	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65 and 67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response and amendments received May 2, 2007 are acknowledged.

Claims 1-64, 66, and 68-71 have been canceled.

Claim 65 has been amended.

Claims 65 and 67 are pending in the instant application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 65, and 67 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of applicant's claim amendments received May 2, 2007.

Specifically, applicant has amended the independent claim to recite that the claimed antibody binds to SEQ ID NO:6, thus rendering the prior grounds of rejection moot.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. The rejection of claims 65 and 67 under 35 U.S.C. 102(e) as being anticipated by Plowman et al., U.S. Patent Application Publication No. US 2003/0050230 (of record, see entire document) as evidenced by Goldsby et al. (Immunology, 5th edition, 2002,

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pages 62-67, of record) and as evidenced by Kuby (Immunology, 1991, page 125) has been withdrawn in view of applicant's claim amendments received May 2, 2007.

Specifically, applicant has amended the independent claim to recite that the antibody binds to SEQ ID NO:6. SEQ ID NO:6 is the GTPase binding domain of PAK4 which is located in the amino terminal region of the full length PAK4 polypeptide of SEQ ID NO:2. The partial sequence disclosed by Plowman et al. in their provisional application does not comprise the amino terminal region of PAK4, and as such does not comprise SEQ ID NO:6. As such, the antibodies disclosed by Plowman et al. cannot reasonably be said to bind SEQ ID NO:6.

5. Applicant's claim amendments received May 2, 2007 have successfully overcome all prior grounds of rejection. However, upon consideration of the additional limitations recited as part of the amendments received May 2, 2007, the following new ground of rejection has been set forth.

6. Claims 65 and 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

As part of applicant's response received May 2, 2007, applicant has amended independent claim 65 to recite a purified antibody "which binds to a GTPase binding domain of human PAK4 serine/threonine kinase, which domain comprises consecutive amino acids having a sequence as set forth in SEQ ID NO:6". Given that the claim recites that the antibody binds a GTPase domain and recites that the GTPase domain comprises SEQ ID NO:6, it is reasonable that the claimed antibody binds the peptide sequence of SEQ ID NO:6.

To support such an amendment, applicant points to lines 35-38 of page 24, lines 11 and 12 of page 25, and lines 20-29 of page 33. The indicated passage on page 24

discloses "...or a monoclonal antibody directed to an epitope of a PAK4 serine/threonine kinase effective to block binding of a PAK4 serine/threonine kinase to a GTP binding protein and a pharmaceutically acceptable carrier capable of passing through a cell membrane", while page 25 discloses "In an embodiment, the GTP binding protein is Cdc42Hs or Rac." And page 33 discloses "The amino terminal putative regulatory domain of PAK4 does not share homology with any other known proteins except for a short sequence resembling a modified GBD/CRIB domain. This conserved sequence of approximately 16 amino acids is found in many proteins that bind Rac and Cdc42Hs (Burbelo et al., 1995). This sequence has been shown to be essential and necessary for interactions of these proteins with the GTPases (Burbelo et al., 1995). The GBD/CRIB domain found on PAK4 in comparison with those found on several other Cdc42Hs/Rac binding proteins is shown in Figure 1D."

As such, it appears that the instant specification discloses antibodies which bind PAK4 and inhibit the binding of a GTPase to PAK4. The specification does not appear to specifically teach that such an inhibitory antibody binds PAK4 at the epitope of Figure 1D, i.e. SEQ ID NO:6. It is well known in the art that antibodies can bind to an antigen and induce conformational changes that prevent ligand binding even when the antibody binds the antigen at a site distant from the ligand binding site. For example, Moradi-Ameli et al. disclose an antibody that binds mitochondrial F1-ATPase and decreases its activity even though the catalytic site of the enzyme is not blocked (see entire document). Similarly, Sun et al. disclose an antibody which induces a conformational change which uncouples lactose from H⁺ transport in the lactose permease of *E. coli* even though the epitope bound by their antibody is not important for enzyme activity (see entire document, particularly the right column of page 1503). As such, an antibody need not bind an antigen at its ligand binding site in order to disrupt antigen-ligand interactions, such as the binding of a GTPase to PAK4.

Given that the instant specification does not appear to explicitly disclose an antibody that binds the epitope consisting of SEQ ID NO:6 and the fact that antibodies can disrupt ligand binding even when binding to an antigen at a site removed from the ligand binding site, it appears that applicant has attempted to claim a subgenus of

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antibodies that block binding of a PAK4 serine/threonine kinase to a GTP binding protein that does not appear to be supported by the disclosure of the instant specification. Therefore, it appears that applicant's claim amendments received May 2, 2007 have introduced new matter into the claimed invention.

7. No claims are allowable.

8. Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.
Patent Examiner
Technology Center 1600
July 16, 2007


7/19/07
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER